

RESPONSE AFTER FINAL REJECTION
EXPEDITED PROCEDURE - RULE 116

Application No.: 10/577,285
Docket No.: 33138-US-PCT
LNG File No. 63618.US

AMENDMENTS TO THE CLAIMS

1. (CURRENTLY AMENDED) A stable pharmaceutical composition of granulocyte-colony stimulating factor (G-CSF), wherein the composition has a pH value in the range from about 4.2 to about 4.8 and comprises:

a therapeutically effective amount of non-glycosylated G-CSF,

a polyol, and

an acid, wherein the composition is free of a surfactant, and wherein the composition is aqueous-a liquid.

2. (ORIGINAL) The composition of claim 1, wherein the pH of the composition is at about 4.4.

3. (CURRENTLY AMENDED) The composition according to claim 1 comprising:

a. a polyol and/or b. a pH buffering system and/or

c. b. one or more pharmaceutically acceptable excipient(s).

4. (CANCELED)

5. (CANCELED)

6. (ORIGINAL) The composition of claim 1, wherein the acid is selected from the group consisting of acetic acid, HCl, maleic acid, glutamic acid, methansulphonic acid, citric acid, malonic acid, lactic acid, sulphuric acid, and phosphoric acid.

7. (ORIGINAL) The composition of claim 6, wherein the acid is selected from the group consisting of acetic acid and HCl.

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8. (CURRENTLY AMENDED) The composition of claim 3 1, wherein the polyol is selected from the group consisting of sorbitol, glycerol, inositol and mannitol.
9. (PREVIOUSLY AMENDED) The composition of claim 8, wherein the polyol is sorbitol.
10. (PREVIOUSLY AMENDED) The composition of claim 9, wherein sorbitol is present in an amount from about 1 % to about 10%.
11. (PREVIOUSLY AMENDED) The composition of claim 9, wherein sorbitol is present in an amount from about 3% to about 8%.
12. (PREVIOUSLY AMENDED) The composition of claim 3 wherein the pH buffering system is selected from the group consisting of acetic acid/acetate and phosphoric acid/phosphate.
13. (PREVIOUSLY AMENDED) The composition of claim 12, wherein the pH buffering system is acetic acid/acetate.
14. (PREVIOUSLY AMENDED) The composition of claim 13, wherein the concentration of acetic acid is in the range from about 0.15 mM to about 15 mM.
15. (CURRENTLY AMENDED) The composition of claim 14 wherein the concentration of 3acetic acid is in a range from about 1.5 mM to about 10 mM.
- 16-18. (CANCELED)
19. (NEW) The composition of claim 1, wherein the pH of the composition is at about 4.2.